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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,848	04/09/2004	Lawrence V. Tannenbaum	СНРРМ 03-22 03	8673
27370	7590 09/28/2006		EXAMINER	
	F THE STAFF JUDGE	LIN, JERRY		
U.S. ARMY	MEDICAL RESEARCH	AND MATERIEL COMMAND		
ATTN: MCMR-JA (MS. ELIZABETH ARWINE) 504 SCOTT STREET FORT DETRICK, MD 21702-5012			ART UNIT	PAPER NUMBER
			1631	
			DATE MAILED: 09/28/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)		
Office Action Summary		10/820,848	TANNENBAUM, LAWRENCE V.		
		Examiner	Art Unit		
		Jerry Lin	1631		
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
WHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANSIONS of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. O period for reply is specified above, the maximum statutory period we are to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION  16(a). In no event, however, may a reply be tim  fill apply and will expire SIX (6) MONTHS from the application to become ABANDONER	l. ely filed the mailing date of this communication.		
Status					
1)⊠	Responsive to communication(s) filed on <u>09 Ap</u>	<u>oril 2004</u> .			
2a)□	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.				
3) 🗌	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Dispositi	on of Claims				
5) 6) 7)	Claim(s) <u>1-13</u> is/are pending in the application.  4a) Of the above claim(s) is/are withdraw Claim(s) is/are allowed.  Claim(s) is/are rejected.  Claim(s) is/are objected to.  Claim(s) <u>1-13</u> are subject to restriction and/or e				
Applicati	on Papers				
10)	The specification is objected to by the Examiner The drawing(s) filed on is/are: a) acce Applicant may not request that any objection to the d Replacement drawing sheet(s) including the correction to the oath or declaration is objected to by the Example 1.	pted or b) objected to by the E lrawing(s) be held in abeyance. See on is required if the drawing(s) is obje	37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).		
Priority u	ınder 35 U.S.C. § 119				
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment	:(s)				
2)	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) No(s)/Mail Date	4) Interview Summary ( Paper No(s)/Mail Dat 5) Notice of Informal Pa 6) Other:	e		

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### **DETAILED ACTION**

#### Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claims 1-12, drawn to a method for assessing ecological risk to receptors, classified in class 702, subclass 19. (Species and Subspecies election required)
  - II. Claim 13, drawn to a method for assessing ecological risk to receptors by removing the epididymis from rodents, classified in class 800, subclass 8.

The inventions are distinct, each from the other because of the following reasons:

2. Group I and II are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different method steps. Since the method steps are different, the inventions have a materially different design, mode of operation, function, and effect. Furthermore, the Groups do not overlap in scope, because the steps define the method and the steps are different. Finally, there is nothing of record to show them to be obvious variants.

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3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

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## Species Election for Group I

4. This application contains claims directed to the following patentably distinct species:

Species A, claim 4, drawn to measuring sperm count.

Species B, claim 5, drawn to measuring sperm motility.

Species C, claim 6, drawn to measuring sperm abnormality.

Species D, claim 7-12, drawn to corroborating he first and second sperm analysis with additional data. (If this Species is elected, a Subspecies election is required).

5. The species are independent or distinct because:

Species A-D are directed to related processes. The related species are distinct if the (1) the species as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the species do not overlap in scope, i.e., are mutually exclusive; and (3) the species as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the species as claimed have different method steps. Since the method steps are different, the species have a materially different design, mode of operation, function, and effect. Furthermore, the

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species do not overlap in scope, because the steps define the method and the steps are different. Finally, there is nothing of record to show them to be obvious variants.

6. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3 generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

## Subspecies Election for Species D

7. This application contains claims directed to the following patentably distinct species:

Subspecies 1, claim 8, drawn to species diversity.

Subspecies 2, claim 9, drawn to population size.

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Subspecies 3, claim 10, drawn to sex ratio.

Subspecies 4, claim 11, drawn to lactation state.

Subspecies 5, claim 12, drawn to pregnancy.

# 8. The Subspecies are independent or distinct because:

Subspecies 1-5 are directed to related processes. The related subspecies are distinct if the (1) the subspecies as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the subspecies do not overlap in scope, i.e., are mutually exclusive; and (3) the subspecies as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the subspecies as claimed have different method steps. Since the method steps are different, the subspecies have a materially different design, mode of operation, function, and effect. Furthermore, the subspecies do not overlap in scope, because the steps define the method and the steps are different. Finally, there is nothing of record to show them to be obvious variants.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3 generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

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is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

## Reply Requirements

9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

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unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

#### Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00am-6:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Representatives are available to answer your questions daily from 6 am to midnight (EST). When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has

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been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199.

JL

MICHAEL BORIN, PH.D PRIMARY EXAMINER